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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,482	02/19/2004	Peilin Guo	JARR-139	5653

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,482	GUO, PEILIN	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 21, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-16 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 are indefinite since it is unclear how mannanoligosaccharide can be in the purified form when it is in a composition comprising other ingredients, including a probiotic microorganism. Thus, claims 1-16 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by De Jong et al. (WO 00/33854).

De Jong et al. discloses a preparation for the "prevention and/or treatment of disorders of the digestive tract" (claim 1). In particular, see claims 1, 3, 6, 7, and 9. The preparation comprises of one or more probiotic microorganisms and one or more non-digestible oligosaccharide (claim 1). Moreover, the preparation may comprise of the combination of one bacterial strain and one yeast strain (claim 6), where the bacterial species may be *Lactobacillus acidophilus* or *Lactobacillus rhamnosus* (page 4, lines 4-6), and the yeast species may be *Saccharomyces cerevisiae* (page 4, lines 7-10). Additionally, De Jong et al. states that "if dead *Saccharomyces cerevisiae* is also used, this is administered in a quantity of 0.5 to 5 g per day" (page 4, lines 26-27). According to the application under examination, mannanoligosaccharides (MOS) are present in "the cell walls of yeast, such as *Saccharomyces cerevisiae*" (page 7, lines 6-7). Similarly, White et al. (Journal of Animal Science, 2002, 80: 2619-2628) notes that *S. cerevisiae* (brewer's yeast) is a source of MOS, and that the MOS content of the yeast is 5.2% (page 2620, first column, fourth paragraph). Thus, a composition comprising *S. cerevisiae* also comprises MOS. In addition to suitable probiotics, De Jong et al. specifies suitable oligosaccharides, which includes fructo-oligosaccharides (FOS) (page 2, lines 28-29). Claim 9 of De Jong et al., recites a ratio of 1 to 5 g oligosaccharides per 10^8 to 10^{11} cells of the probiotic, and indicates that "the total concentration of probiotics is 10^6 to 10^{12}...live cells per gram of total product" (page 4, lines 20-21). Depending on the masses of *S. cerevisiae*, fructo-oligosaccharide, and *L. acidophilus* or *L. rhamnosus* used in a preparation meeting the requirements of De Jong et al., limitations recited in claims 4-8 of the application under examination are met.

Example II, a synbiotic bar, is one suitable preparation (page 8, line 5-8). The 23 gram bar comprises of 1 gram of *L. rhamnosus*, 0.5 gram of brewer's yeast, and 5 gram of an oligosaccharide. Thus, the bar of Example II comprises as few as $2.3 * 10^7$ live cells (23 g total product * 10^6 live cell/g total product). A colony forming unit (CFU) can comprise of only a single cell, thus the bar of Example II may comprise of $2.3 * 10^7$ CFU of *L. rhamnosus*. Since De Jong et al. specifies that 0.5 to 5 g of dead *S. cerevisiae* may be administered per day (page 4, lines 26-27), a daily intake of a one to ten synbiotic bars is appropriate. If 5 g of *S. cerevisiae* is administered in a day, 260 mg MOS is administered daily (5 g yeast * 0.052). Moreover, a daily intake of ten synbiotic bars results in a daily intake of 260 mg MOS, $2.3 * 10^8$ CFU of *L. rhamnosus*, and 50 grams of oligosaccharides (transgalacto-oligosaccharides).

Additionally, ten synbiotic bars combined together would be considered a "composition for improving gastrointestinal tract health", where said composition comprises 260 mg MOS, and $2.3 * 10^8$ CFU of *L. rhamnosus*.

Applicant's arguments have been fully considered but they are not persuasive. The claims as amended recite that "mannanoligosaccharide is in one of a purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans." As amended, the claims do not require that mannanoligosaccharide must only be in a purified form. Applicant asserts that De Jong et al. does not describe a composition containing MOS in any of the forms recited in the claims as amended. Though De Jong et al. does not teach that the mannanoligosaccharide is in a purified form, it is respectfully noted that the reference does indeed teach a mannanoligosaccharide in a bonded or non-bonded complex with proteins, or a mannanoligosaccharide in a matrix with beta-glucans. Mannanoligosaccharide is clearly in a

bonded or non-bonded complex with proteins when present in yeast, since yeast comprises of proteins. Furthermore, yeast cell walls are composed of beta-glucans (see US 4,810,646, column 1, lines 32-34), thus the yeast cell can be considered a matrix comprising mannanoligosaccharides and beta-glucans. Thus, mannanoligosaccharide that is presented in yeast still meets the limitations of claims under examination.

With respect to the amendment of claim 6 requiring that the composition contains between 300 mg to about 10 mg mannanoligosaccharide, De Jong et al. still teaches this limitation since, depending on the masses of *S. cerevisiae*, fructo-oligosaccharide, and *L. acidophilus* or *L. rhamnosus* used in a preparation meeting the requirements of De Jong et al., limitations recited in claims 4-8 of the application under examination are met. A composition meeting the requirements of De Jong et al. still meets the requirements of claim 6 since the amount of mannanoligosaccharide is dependent on the total mass of the De Jong composition, and there is no limit as to the quantity that can be produced of the De Jong composition. Applicant indicates that the previous office action noted that the maximum amount of MOS that is present in the yeast cell walls in the compositions described by De Jong is approximately 260 mg. However, the June 21, 2005 office action noted that "a daily intake of ten symbiotic bars results in a daily intake of 260 mg MOS" (page 4, last sentence), therefore not placing any limitations as to the maximum amount of MOS present in the composition. Moreover, the daily intake of 260 mg MOS is in reference to an example disclosed in De Jong et al, and does not place any limitation as to the daily intake of mannanoligosaccharides in the practice of the De Jong invention.

Thus, holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. in view of Van Laere et al. (WO 02/051264).

As discussed above, De Jong et al. anticipates claims 1-8, 11, and 14. However, De Jong et al. does not expressly disclose a composition comprising purified mannanoligosaccharide.

Van Laere et al. discloses a nutritional composition having beneficial effect in the gastrointestinal tract, which comprises of 0.5-10 g of a non-digestible oligosaccharide, such as manno-oligosaccharide, which is another spelling for mannanoligosaccharide (abstract). Manno-oligosaccharide is preferably obtained from natural sources, either by direct extraction or by hydrolysis (page 8, lines 34-38), thus the manno-oligosaccharide present in the Van Laere composition is in purified form. The manno-oligosaccharide "...may (further) help to maintain and/or restore the intestinal flora, which again may result in a synergistic effect" (page 9, lines 7-8). Additionally, the Van Laere composition "...may advantageously also contain probiotic organisms such as bifidobacteria, lactobacilli and other lactic acid bacteria..." (page 9, lines 12-13).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included purified mannanoligosaccharide in the composition of De Jong et al. One of ordinary skill in the art would have been motivated to do this since mannanoligosaccharide helps to maintain/restore the intestinal flora and is a known ingredient in a nutritional composition having a beneficial effect on gastrointestinal tract health. Thus, a holding of obviousness is clearly required.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. and Van Laere et al.

As discussed above, De Jong et al. and Van Laere et al. render claims 1-8, 11, and 14 obvious.

De Jong et al. and Van Laere et al. do not expressly disclose administering fructooligosaccharide to achieve a daily intake ranging from 100 mg to 25 g, or the daily intake of mannanoligosaccharide as recited in claims 12 and 13.

Since a daily intake of $2.3 * 10^8$ CFU of *L. rhamnosus* is appropriate (based on information about the synbiotic bar), and given claim 9 of De Jong et al., a minimum of 2.3 g of oligosaccharide, such as fructooligosaccharide, is suitable for daily intake.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have administered 100 mg to 25 g of fructooligosaccharides per day by the intake of a preparation disclosed in De Jong et al.

One of ordinary skill in the art would have been motivated to do this since De Jong et al. indicates in claim 9 a wide range of suitable proportions of oligosaccharide to probiotic.

Additionally, the selection of a particular daily dose (whether of fructooligosaccharides, *S. cerevisiae*, and *L. rhamnosus* or *L. acidophilus*) would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the daily dosages of the De Jong composition administered to a patient such that the limitations of claims 12 and 13 are met.

One of ordinary skill in the art would have been motivated to do this since the daily dosages of drugs must be tailored to each patient, depending on patient weight, age, needs, etc. Thus, the daily dosage of the De Jong composition can be greater than the dosage disclosed in Example II in De Jong et al. The selection of a particular daily dose would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention. Furthermore, De Jong et al. does not provide any limitations as to the daily intake of the composition. Applicant indicates that the previous office action noted that the maximum amount of MOS present in the yeast cell walls in the compositions described by De Jong is approximately 260 mg. However, the June 21, 2005 office action states that "a daily intake of ten symbiotic bars results in a daily intake of 260 mg MOS" (page 4, last sentence). The daily intake of 260 mg MOS is in reference to an example disclosed in De Jong et al, and thus does not place any limitation as to the daily intake of mannanoligosaccharides in the practice of the De Jong invention.

Applicant's arguments have been fully considered but they are not persuasive. Since De Jong et al. and Van Laere et al. do teach a composition comprising MOS in the forms recited in the claims, the claims discussed above are obvious in view of De Jong et al. and Van Laere et al.

A holding of obviousness is clearly required.

Claims 1-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. and Van Laere et al. as applied to claims 1-8, 11, and 14 above, and further in view of Sorkin, Jr. (US 5,952,393).

As discussed above, De Jong et al. and Van Laere et al. render claims 1-8, 11, and 14 obvious.

De Jong et al. and Van Laere et al. do not expressly disclose compositions comprising at least one formulation aid recited in claims 9 and 10.

Sorkin, Jr. discloses a composition comprising "pharmaceutically acceptable formulation aids, such as diluents, stabilizers, binders, buffers, lubricants, coating agents, preservatives, emulsifiers and suspension agents" (column 2, lines 11-15).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included at least one of the formulation aid in the preparation taught by De Jong et al., such as those listed in Sorkin, Jr.

One of ordinary skill in the art would have been motivated to do this since the compositions taught by De Jong et al., Van Laere et al. and Sorkin, Jr. are for treatment in humans. Furthermore, the formulation aids are safe for administration in humans since the formulation aids are "pharmaceutically acceptable". These formulation aids would not have interfered with the activities of the De Jong preparation, as they had been found suitable for the Sorkin, Jr. preparation. Applicant's arguments with respect to these rejections have been fully considered but they are not persuasive. As discussed above, De Jong anticipates 1-8, 11, and 14,

and thus teaches a composition combining probiotics, MOS provided in the forms recited in claim 1, and fructooligosaccharides. Furthermore, De Jong et al. and Van Laere et al. also meet the limitations of claim 1. Thus, Sorkin, Jr. is provided solely to meet the deficiencies of De Jong et al. and Van Laere et al. pertaining to the presence of formulation aids. Thus, a holding of obviousness is clearly required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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sef